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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/412,284 10/05/99 ALLAWAY

G 43966-CA-PCT

HM22/1219

JOHN P WHITE
COOPER AND DUNHAM LLP
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER

PARKIN, J

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/412,284

Applicant(s)
Allaway, G., et al.

Examiner
Jeffrey S. Parkin, Ph.D.

Group Art Unit
1648



☒ Responsive to communication(s) filed on 5 Oct 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 7-14 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

☒ Claim(s) 7-14 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial No.: 09/412,284
Applicants: Allaway, G., et al.

Docket No.: 43966-CA-PCT
Filing Date: 10/05/99

Detailed Office Action

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the Preliminary Amendments filed 05 October, 1999, and 19 January, 2000, wherein claims 1-6 were canceled without prejudice or disclaimer and new claims 7-14 introduced.

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Information Disclosure Statement

2. The information disclosure statements filed 19 January, 2000, and 22 May, 2000, have been placed in the application file and the information referred to therein has been considered.

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Drawings

3. The drawings filed in this application are objected to by the Draftsperson under 37 C.F.R. §§ 1.84 or 1.152 as indicated. These drawings are acceptable for examination purposes only. Formal drawings with the appropriate corrections will be required when the application is allowed. Applicants are reminded to amend the specification (i.e., brief description of the figures including panel descriptions) if necessary when submitting corrected drawings.

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35 U.S.C. § 112, Second Paragraph

4. Claims 9 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to a "CD+ cell" is vague and indefinite since this does not appear to reference an art-recognized cell type and there is no definition of such a cell type in the specification. Accordingly, the metes and bounds of the patent protection desired cannot be ascertained. Applicants may

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obviate the rejection by directing the claim language toward
"CD4⁺ cell".

35 U.S.C. § 112, First Paragraph

5 5. The following is a quotation of the first paragraph of 35 U.S.C.
§ 112:

10 The specification shall contain a written description of the
invention, and of the manner and process of making and using it, in
such full, clear, concise, and exact terms as to enable any person
skilled in the art to which it pertains, or with which it is most
nearly connected, to make and use the same and shall set forth the
best mode contemplated by the inventor of carrying out his
invention.

15 6. Claims 7-14 are rejected under 35 U.S.C. § 112, first paragraph
because the specification does not reasonably enable any person
skilled in the art to which it pertains, or with which it is most
nearly connected, to make and/or use the invention commensurate in
scope with these claims. The legal considerations that govern
20 enablement determinations pertaining to undue experimentation are
disclosed in *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988) and *E*
parte Forman 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The
courts concluded that several factual inquiries should be
considered when making such assessments including the quantity of
25 experimentation necessary, the amount of direction or guidance
presented, the presence or absence of working examples, the nature
of the invention, the state of the prior art, the relative skill of
those in that art, the predictability or unpredictability of the
art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593
30 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to
provide adequate guidance pertaining to a number of these
considerations as follows: 1) The breadth of the claimed invention
is exceedingly large and fails to receive adequate support in the
specification. The claims do not provide any structural
35 limitations whatsoever on the inhibitory agent. Thus, any chemical

compound, including *inter alia*, organic compounds, peptidomimetics, and antibodies, may be encompassed by the claims. However, the specification fails to guide the skilled artisan toward those compounds that can reasonably be expected to retain the desired inhibitory activity. 2) The disclosure fails to provide sufficient guidance pertaining to the structural characteristics of those compounds that are capable of inhibiting macrophage- or T cell-tropic isolates in a specific manner. The disclosure is silent pertaining to the identification of a common inhibitor motif in the agent of interest. 3) The disclosure also fails to provide any guidance pertaining to the molecular determinants of those regions of the viral envelope and cell surface receptor that are involved in fusion. This might enable the skilled artisan to rationally direct molecules toward certain active sites in the fusion reaction. However, without sufficient guidance pertaining to a suitable molecular target, the skilled artisan has only been extended an undue invitation to further experimentation to try to ascertain which compounds might function in the desired manner. 4) The prior art is unpredictable and fails to provide sufficient illumination pertaining to the structural constraints governing viral-cell fusion. Most successful antiviral agents have been directed against well-characterized enzymatic sites (Hirsch et al. 1997). For instance, protease inhibitors are directed toward an enzymatically active site that has been identified through x-ray crystallography structures of the enzyme. However, no such guidance is available for the current target of interest. 5) The disclosure fails to provide sufficient working embodiments to enable the breadth of the claimed invention. 6) Legal precedent dictates that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 1824 (C.C.P.A. 1970). *In re Vaeck*, 20 U.S.P.Q.2d 1438 (C.A.F.C.

1991). *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. 214, 21 (C.C.P.A. 1976). Thus, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

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35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 8. Claims 11-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vanini et al. (1992). This teaching discloses the preparation and characterization of syncytia-inhibiting affinity-purified antibodies and their methods of use. These antibodies are capable of inhibiting fusion between a T-cell tropic HIV-1 isolate (designated LAV) and CD4⁺ cells. Thus, absent evidence to the contrary, this agent appears to meet all of the claimed limitations.

30 9. Claims 7-10 are rejected under 35 U.S.C. § 102(a) as being anticipated by Verrier et al. (1997).¹ This teaching discloses the preparation and characterization of syncytia-inhibiting affinity-purified antibodies and their methods of use. These antibodies are

¹ Applicants are advised that priority cannot be extended to Application Serial No. 08/475,515, filed 07 June, 1995. Accordingly, the effective filing date for the purposes of applying art is that of Application Serial No. 08/973,601, filed 16 March, 1998.

capable of inhibiting fusion between a macrophage-tropic HIV-isolate (designated BX08) and CD4⁺ cells. These reagents do not affect fusion between T-cell-tropic isolates. Thus, absent evidence to the contrary, this agent appears to meet all of the claimed limitations.

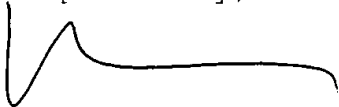
Correspondence

10. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

11. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

12. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

15 December, 2000